



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/102,390	08/05/1993	ARTHUR I. SKOULTCHI	CELG-0003-CONT	8522
22506	7590	07/27/2011	EXAMINER	
Vedder Price, PC 1401 I Street, NW Suite 1100 Washington, DC 20005			CHEN, SHIN LIN	
			ART UNIT	PAPER NUMBER
			1632	
			MAIL DATE	DELIVERY MODE
			07/27/2011	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 08/102,390	<b>Applicant(s)</b> SKOULTCHI, ARTHUR I.
	<b>Examiner</b> SHIN LIN CHEN	<b>Art Unit</b> 1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 09 January 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 106-109 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 106 is/are allowed.
- 6) ☒ Claim(s) 107-109 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |  |
|--|--|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br/>Paper No(s)/Mail Date _____.</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)<br/>Paper No(s)/Mail Date. _____.</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application</p> <p>6) <input type="checkbox"/> Other: _____.</p> |
|--|--|

### **DETAILED ACTION**

The decision by Board of Patent Appeals and Interferences (BPAI) filed 1-9-07 ordered that any action taken by the examining corps subsequent to June 24, 2004 is a nullity (page 3).

The decision by BPAI filed 6-24-03 ordered that CELL GENESYS. INC. is not entitled to a patent containing claims 105, 110, 111 and 112. Claims 3, 4, 8, 21, 24, 27, 31, 40-51, 55 and 58 of ARS's patent 5,272,071, and claims 106 of CELL GENESYS's application 08/102,390 have NO interference-in-fact (see page 2).

Claims 106-109 are pending and under consideration.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 107-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chappel, Scott C., 1993 (US Patent No. 5,272,071 A).

Claims 107-109 are directed to a method of causing a mammalian cell to express a gene normally not expressed by said cell or to increase the level of gene expression normally expressed by said cell, comprising inserting a DNA construct through homologous recombination into the genome of said cell in proximity to said gene, said construct comprising at least one of an amplifiable gene, other regulatory sequence, or both, and DNA homologous

Art Unit: 1632

with DNA of a region in proximity to said gene, whereby said gene is expressed in said cell, or whereby said gene is expressed in said cell in which said DNA construct is incorporated.

Chappel teaches a method of activating a predominantly normally transcriptionally silent gene within the genome of a cell line to express the gene product, comprising inserting a DNA construct into said genome by homologous recombination, said DNA construct comprising an expressible amplifiable gene, a DNA regulatory segment and a DNA targeting segment homologous to a region of said genome within or proximal to said gene, wherein said construct is inserted such that said regulatory segment is operably linked to said gene of interest (e.g. claims 1 and 8).

Chappel does not specifically teach increasing the level of gene expression of a gene normally expressed by the cell.

It would have been prima facie obvious for one of ordinary skill in the art at the time of the invention to increase gene expression level of a gene normally expressed in a cell because activating predominantly normally transcriptionally silent gene would increase gene expression level of a gene and the gene that is predominantly silent could have a basal transcription activity. Homologous recombination of the DNA construct into a cell's genome as taught by Chappel would increase gene expression of the gene of interest in said cell regardless of whether said gene is silent or normally expressed in said cell.

One having ordinary skill in the art at the time the invention was made would have been motivated to do so in order to activate gene expression via homologous recombination in a cell as taught by Chappel with reasonable expectation of success.

***Conclusion***

Claims 107-109 are rejected. Claim 106 is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for this group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Application/Control Number: 08/102,390

Page 5

Art Unit: 1632

Shin-Lin Chen  
/Shin-Lin Chen/  
Primary Examiner  
Art Unit 1632